REMARKS

Entry of the foregoing, and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.116, and in light of the comments which follow, are respectfully requested.

By the foregoing amendment, Claims 16, 19, 31 and 32 have been amended to clarify the reference to the amino acid sequences as being in the alternative. Support for these amendments is present in the specification, e.g., at page 2, third full paragraph.

Turning now to the Official Action, Claims 16, 19, 31 and 32 stand rejected under 35 U.S.C. § 101, as allegedly lacking a "specific and substantial credible utility", and under 35 U.S.C. § 112, first paragraph, since the claims are allegedly not adequately supported by either a clear asserted utility or a well-established utility. Applicant respectfully traverses these rejections for at least the following reasons.

At the outset, it is respectfully submitted that a proper *prima facie* rejection based upon lack of utility has not been established in the Official Action.

As set forth, e.g., in the MPEP at § 2107, a proper *prima facie* rejection based upon lack of utility must establish that there is no specific and substantial utility for the invention as claimed, either because Applicant has failed to set forth such a utility or because there is no well-established utility for the invention. See, e.g., MPEP §§ 2107.01(I) and 2107.02(II). Where Applicant has asserted a specific and substantial utility, a presumption of utility generally exists. See, e.g., MPEP § 2107.02(III), citing a number of court decisions, including *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977); *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995); *and, In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

As clearly stated in the MPEP § 2107.02(III)(B), "[w]here an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being 'wrong,' even when there may be reason to believe that the assertion is not entirely accurate. Rather, Office personnel must determine if the assertion of utility is credible (*i.e.*, whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided)." In addition, "[a]n assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." To overcome the presumption of utility, Office personnel must further establish that it is more likely than not that one of ordinary skill in the art would doubt the truth of the statement of utility. See MPEP § 2107.02(III)(A) and *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

It is further noted that a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging an asserted utility under 35 U.S.C. 101. See MPEP § 2107.02(III)(B).

In the present case, Applicant respectfully submits that the present application clearly provides ample disclosure of a "specific and substantial utility". For example, as disclosed in a number of the original claims, Applicant has indicated that the invention possesses a number of specific and substantial utilities, including those specified in original claims 3, 4, 10, 12 and 22 to 31. Among these utilities are the reduction or prevention of negative effects on brain tissue caused by epileptic seizures (claim 10); contributing to axonal regeneration and/or restoration of synaptic integrity and functions (claim 12); the amelioration of pathological pain syndromes (claim 22); ameliorating the learning and memory functions in healthy persons and persons with reduced learning and memory functions (claim 24); ameliorating certain psychiatric disorders (claims 27-29) or brain function deficiencies (claim 30).

Based at least upon this information, Applicant respectfully submits that the present application adequately specifies a "specific and substantial utility" to satisfy the requirements of 35 U.S.C. § 101.

It is further asserted in the Official Action at page 5 that Applicant's specification allegedly fails to "disclose a credible 'real world' use for the neurotrypsin proteins". Skolnick et al further appears to be relied upon to allegedly support the position that knowledge of protein structure alone is insufficient to determine function characteristics.

To the extent that the Examiner may intend that the specific utilities disclosed by Applicant are allegedly not "credible" based upon the Skolnick et al article, Applicant strongly disagrees that the reasoning provided in the Official Action properly supports a rejection under 35 U.S.C. § 101.

In the first instance, nothing in Skolnick et al appears to directly relate to Applicant's claims, specifically the isolated neurotrypsins according to SEQ ID NOS: 2 or 4 or the method for the development of pharmaceutical drugs based upon these sequence identifiers. Instead, Skolnick et al appears to simply refer to structure-function relationships in a general way without reference to isolated neurotrypsins or proteins having the coded amino acid sequences according to Applicant's claims. As such, the information relied upon from this article does not provide any basis to suggest that one skilled in the art would more likely than not doubt the utility (or utilities) specified by Applicant.

Moreover, Skolnick et al does not appear to unequivocally support the statement relied upon in the Official Action since it is also noted that "a much more detailed analysis of the SCOP database . . . finds a broad function-structure correlation for some structural classes". (see the first and second sentences of the third paragraph in Box 2, page 36, noted in the Official Action). It therefore appears that the general information referred to in Skolnick et al cannot reasonably be relied upon to dispute the credibility of Applicant's asserted utility (or utilities). In the absence of such support, the rejections must be considered to be improper

since there is no clearly apparent reason to challenge the credibility of Applicant's asserted utility.

As concerns the rejections under 35 U.S.C.§ 112, first paragraph, based upon the assertion that the claims are allegedly not adequately supported by either a clear asserted utility or a well-established utility, Applicant respectfully submits that these rejections are also improper for at least the foregoing reasons.

For reasons noted above, withdrawal of the rejections under 35 U.S.C. § 101 and § 112, first paragraph, is requested.

Claims 16, 19, 31 and 32 stand further rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicant respectfully traverses these rejections for at least the following reasons.

In the Official Action, it is asserted that the terms "isolated neurotrypsins" and "isolated proteins" are unclear since the claims appear to be directed to mixtures of polypeptides. Applicants respectfully disagree.

As amended, Claims 16 and 19 refer to the sequences of SEQ ID NOS: 2 or 4 in the alternative. As such, the claims do not refer to mixtures of polypeptides according to both sequence identifiers.

With regard to Claim 32, it is noted that the presently amended claim incorporates the Examiner's helpful suggestion to change "of" to "from".

For at least the foregoing reasons, Claims 16, 19, 31 and 32 are believed to be clear within the meaning of the second paragraph of 35 U.S.C. § 112. Withdrawal of the second paragraph rejections is requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is requested.

If the Examiner has any questions concerning this response, or the application in general, she is invited to telephone the undersigned at the telephone number indicated below.

Respectfully submitted,

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Date: January 13, 2003

Attachment to Reply and Amendment Filed January 13, 2003
Marked up version of Claims 16, 19, 31 and 32

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16. (three times amended) Isolated neurotrypsins having the amino acid sequences of [formulas I and II] formula I or formula II:

I: neurotrypsin of the human (SEQ ID NO: 2); [and] or

II: neurotrypsin of the mouse (SEQ ID NO: 4).

19. (three times amended) A method for the development of pharmaceutical drugs comprising,

[providing isolated] isolating proteins having the coded amino acid sequences of SEQ ID [NOS] NO: 2 or SEQ ID NO: 4 and using said proteins as targets for said pharmaceutical drugs.

31. (twice amended) The method of claim 19, wherein said pharmaceutical drugs inhibit or enhance the catalytic activity of the coded proteins having the coded amino acid sequences of SEQ ID [NOS] NO: 2 or SEQ ID NO: 4.

32. (twice amended) The method of claim 19, wherein said proteins having the coded amino acid sequences of SEQ ID [NOS] NO: 2 or SEQ ID NO: 4 are obtained by purification [of] from a natural source, or are produced by recombinant protein expression using eucaryotic or procaryotic expression vectors, followed by purification of the proteins.